Appendix E

APPENDIX E
LEAD RISK CHARACTERIZATION

E-1 Introduction

Lead was identified as a chemical of potential concern (COPC) based on the COPC selection process described in Section 3.3 of the main text of this Baseline Human Health Risk Assessment (BHHRA) report. This appendix presents the results of blood lead modeling that was conducted to assess the potential adverse health effects associated with exposure to lead. This approach is consistent with that used in the BHHRA for the Lower Passaic River Study Area (LPRSA) (AECOM, 2017).

The selection of COPCs for lead is summarized below and in Table E-1.

- **Accessible Surface Sediment.** The maximum detected concentration of lead is 2,190 mg/kg. As discussed in Section 3.3.4 of the main text of this BHHRA report, USEPA's current residential RSL (USEPA 2019) for lead in soil is 400 mg/kg, based on the regulatory target of no more than 5% of young children in a population having a blood-lead level exceeding 10 µg/dL. USEPA now recommends targeting blood lead levels below 10 µg/dL; in fact, USEPA (2017b) recommends updates to lead methodologies and includes examples targeting a blood level of 5 µg/dL. Therefore, as recommended by USEPA and NJDEP (2019), 200 mg/kg is used as the screening level for lead in sediment, which is lower than the maximum detected concentration in sediment.
- Therefore, lead was selected as a COPC in accessible surface sediment.
- **Surface Water.** The maximum detected concentration of lead in surface water, 8.5 µg/L, is below the EPA drinking-water action level of 15 µg/L.[1] Therefore, lead was not selected as a COPC in surface water.
- **Fish Tissue.** For all species, the maximum detected concentration of lead in fish, 0.152 mg/kg, is below the Federal Drug Administration (FDA) action level for lead in crustacea of 1.5 mg/kg (FDA, 2007). Therefore, lead was not selected as a COPC in fish.
- **Crab Tissue.** Lead was detected below the FDA action level for lead in crustacea of 1.5 mg/kg (FDA, 2007) in samples of muscle tissue, and samples of muscle and hepatopancreas combined. However, lead was detected at a maximum concentration of 2.52 mg/kg in samples of hepatopancreas tissue, which is above the action level of 1.5 mg/kg. Therefore, lead was selected as a COPC in crab hepatopancreas tissue, even though it is very unlikely that an individual would consume only the hepatopancreas, especially on any kind of regular basis.

Receptors evaluated in this assessment include an angler/sportsman, swimmer, wader, boater, and worker. Receptors are evaluated by age group:

- The adult is assumed to be >18 years of age, and is assumed to crab, swim, wade, or boat on Newark Bay.

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1 https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations#Inorganic

- The child is considered to be 1 to <7 years of age, and this age group is considered to be able to swim or wade in Newark Bay, or to eat crab brought home by an angler/sportsman.
- The adolescent is considered to be 7 to <19 years of age, and is assumed to crab, swim, wade, or boat on Newark Bay.

Each receptor group is considered separately; however, exposures via multiple pathways for the same receptor are included in this assessment. For example, the angler/sportsman (adult and adolescent) is assumed to be exposed via direct contact with sediment and via consumption of crab.

The EPA Integrated Exposure Uptake Biokinetic (IEUBK) model (Version 1.1, Build 11) was used to quantify potential exposures to lead for children younger than 7 years of age (USEPA, 1994a,b). This model correlates lead levels in the environment to blood lead levels (PbB) in children. The IEUBK model comprises a four-step process that predicts PbBs associated with environmental lead exposures from multiple sources and routes for a population of children (0–84 months of age). For this assessment, PbBs were estimated for children 12–72 months, which is the same 6-year time period as for the child scenario evaluated in the main text of the BHHRA report for other COPCs.

The model developed by Bowers et al. (1994) was used to quantify exposures to lead for adolescent and adult receptors. Similar to the IEUBK model, the Bowers et al. model accounts for exposure to lead present in multiple environmental media, including air, soil, and water. The component of the model for soil is the same as that used in the EPA Adult Lead Methodology (ALM) spreadsheet (USEPA, 2001, 2017a). The ALM could not be used on its own because it does not account for exposure to lead via pathways other than soil (e.g., food).

While the preferred lead risk assessment tool for non-residential exposure scenarios is the Adult Lead Methodology, the Bowers model does accommodate non-soil exposures. And in fact, the Bowers et al. (1994) model was not included in US EPA review (2001) of adult lead models because of the similarity between the Bowers and ALM models, i.e., the basic algorithms for the Bowers model form the basis for the ALM model (USEPA, 2001).

E-2 Exposure Assessment

As discussed in Section 4.4 of the main text of the BHHRA report, the exposure-point concentration (EPC) represents the concentration in each environmental medium to which a receptor is assumed to be exposed during the exposure period. Unlike for other chemicals, the arithmetic mean concentration is used as the EPC in evaluating exposures (USEPA, 2003, 1994a). Table E-1 provides the summary statistics and the selected EPCs:

- **Accessible Surface Sediment.** Lead concentrations ranged from 26.1 mg/kg to 2,190 mg/kg, with an average of 205.7 mg/kg. The average concentration is slightly above the currently recommended screening level for lead in surface soil of 200 mg/kg (USEPA, 2017b; USEPA and NJDEP, 2019).
- **Blue Crab (Hepatopancreas).** Lead concentrations ranged from less than 0.0257 mg/kg to 2.52 mg/kg, with an average of 0.411 mg/kg. The average concentration is below the FDA action level for lead in crustacea of 1.5 mg/kg (FDA, 2007).

Exposure was assessed for anglers/sportsmen, swimmers, waders, and boaters (child, adolescent, and adult, as applicable), as well as adult workers. Exposure assumptions required for the IEUBK model and/or ALM include body weight, exposure frequency, exposure duration, averaging time, sediment ingestion rate, and crab ingestion rate. In the main BHHRA report, separate assumptions were made for both the central tendency exposure (CTE) and the reasonable maximum exposure (RME); however, for purposes of this assessment of lead exposure, only RME assumptions were used. The values used for these parameters in the lead models are summarized in Table E-2. With two exceptions, these are the same values used to evaluate other COPCs for the NBSA. The rationale and references for these exposure parameters are found in Tables 4-2 through 4-6, 4-8, and 4-10 of the main BHHRA report.

The first exception is the exposure frequency for child swimmers and waders exposed to sediment. As described in Section 4.3.7.6 of the main BHHRA report, child swimmers and waders under the RME scenario are assumed to be exposed to sediment 1 day per week for 3 months, or 13 days per year. However, the IEUBK model assumes exposure occurs for 365 days per year and cannot be changed in the model. Accordingly, an exposure frequency of 365 days per year was used.

The second exception is the averaging time for adolescent and adult anglers, swimmers, waders, and boaters exposed to sediment. As also described in Section 4.3.7.6, adolescent and adult crabbers under the RME scenario are assumed to be exposed to sediment 2 days per week for 3.5 months, or 30 days per year. For adolescent and adult waders, simmers, and waders, exposure to sediment was assumed to occur 3 days per week or 1 day per week for 3 months, or 39 or 13 days/year respectively, under the RME scenario. However, for purposes of predicting blood level levels from exposure to sediment, it is more appropriate to use the actual duration of exposure, i.e., 105 days or 90 days, as the averaging time, rather than the standard assumption of 365 days.

E-3 Estimating Potential Exposures of Children to Lead

As noted above, the IEUBK model was used to calculate PbBs for the child (1 to <7 years) age group. Calculations were performed using the IEUBK v1.1, Build 11 software. Key assumptions in the IEUBK model are discussed below.

E-3.1 Sediment

The mean lead concentration in accessible surface sediment is 205.7 mg/kg, which is applicable to the swimmer and wader receptors. The child angler/sportsman is assumed to not participate in crabbing, and boating is considered to be not applicable to a child; thus, no direct contact with accessible surface sediment is assumed. The child swimmer and wader are assumed to ingest 0.1 grams of sediment per day (g/day). Due to default parameters inherent in IEUBK v1.1, Build 11, averaging times and exposure frequencies of 365 days per year were used, even though RME child swimmers and waders in the main BHHRA report are assumed to be exposed to sediment 1 day per week for 3 months. Accordingly, the estimated blood lead concentrations for the child wader (and swimmer) were based on exposure 365 days per year, overstating the contribution of lead in sediment to child blood lead levels. Since the mean lead concentration in sediment is 205.7 mg/kg, which is only slightly higher than the 200 mg/kg screening level recommended in EPA’s comments, any time-weighted concentration based on average state or county data would be below 200 mg/kg.

E-3.2 Air

Exposure to airborne particulates from sediment is not a complete pathway in the conceptual site model for Newark Bay. Thus, the air concentration was entered as zero in this assessment.

E-3.3 Diet

IEUBK v1.1, Build 11 assumes an average ingestion of lead from diet of about 2 µg/day (1.95 to 2.26) for each age range within the child group. The model default value of 50% for fractional absorption (uptake) of lead ingested from the diet was used in the “GI Values/Bioavailability” option of the IEUBK software

(USEPA, 1994a). A crab ingestion rate of 7g/day ($6.9\overline{6}$ g/day) for the child angler/sportsman was used, which is one-third of the adult crab ingestion rate (USEPA, 2012). Therefore, excess crab intake was calculated as:

$$\frac{EPC_{Pb_{crab\ hepatopancreas}} \cdot IR_{crab\ hepatopancreas} \cdot EF_{crab\ hepatopancreas}}{AT_{crab\ hepatopancreas}} = \frac{0.411 \cdot 6.9\overline{6} \cdot 365}{365} = 2.863\ ug/day$$

Here:

$EPC_{Pb_{crab\ hepatopancreas}}$ is Exposure Point Concentration in mg/kg,

$IR_{crab\ hepatopancreas}$ is Ingestion Rate in g/day,

$EF_{crab\ hepatopancreas}$ is Exposure Frequency in days/year, and

$AT_{crab\ hepatopancreas}$ is Averaging Time in days/year.

For the purpose of simplicity and to obtain a more conservative estimate of risk from diet, it was assumed that the consumption of crab was in excess of the default consumption of food. In other words, the dietary lead intake used in this assessment was the sum of the default lead intake plus the intake due to crab, as shown in the following table.

Age Group	IEUBK Default (µg/day)	Total Intake (µg/day)
1-2	1.96	4.823
2-3	2.13	4.993
3-4	2.04	4.903
4-5	1.95	4.813
5-6	2.05	4.913
6-7	2.22	5.083

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E-3.4 Surface Water

As discussed previously, lead is not a COPC for the surface-water pathway for Newark Bay. Therefore, the lead concentration was entered as zero in this assessment.

E-4 Estimating Potential Exposures of Adolescents and Adults to Lead

The EPA's recommended approach for assessing nonresidential adult risks associated with lead exposure uses a method that relates soil lead intake to PbBs in women of child-bearing age (USEPA, 2003). The predicted PbB is then used to predict the PbB of an exposed fetus. This approach assumes that cleanup goals protective of a fetus will also be protective of male and female adult workers (USEPA, 2001). While EPA's ALM is useful for assessing most sites where other than residential exposures may occur, the ALM spreadsheet provided on the USEPA website addresses only the soil pathway. As noted, the basic algorithms for the Bowers et al. (1994) model were used as the basis for the current ALM. Accordingly, the adult lead exposure model of Bowers et al. (1994) was adapted to calculate the PRG and to estimate the PbB in adults to evaluate potential exposures to lead via crab ingestion, as well as accessible surface sediment. As with EPA's ALM, the Bowers et al. (1994) model uses a biokinetic slope factor (BKSF) to represent lead biokinetics and an exposure model in which all exposure pathways, other than soil ingestion, are represented by a background PbB concentration. The adult lead model was applied to adolescents (7 to <19 years) in accordance with USEPA recommendations.[2]

Model inputs are presented in Table E-3. The model incorporates ingestion and absorption rates specific to each potential exposure pathway based on the assumption that there is a baseline PbB in the U.S. adult population that reflects typical exposures, primarily due to lead in the diet. The ALM is different from the IEUBK model, in that the BKSF is used to relate total uptake of lead in adults to blood lead, rather than the multicompartment distribution model used in the IEUBK model (Bowers et al. 1994). The Bowers model defines the adult PbB as the baseline PbB (PbB0) plus the increase in PbB from lead uptake from other sources, as follows:

$$PbB_{adult} = \left(BKSF \times \sum_{i=1}^{n} uptake_i \right) + PbB_0 \tag{1}$$

where:

PbBadult	=	Geometric mean of adult blood lead concentration (µg/dL)
$Uptake_i$	=	Medium-specific lead incidental ingestion uptake
BKSF	=	Biokinetic slope factor [(µg/dL) per (µg/day)]
PbB0	=	Baseline blood lead concentration (µg/dL).

The lead uptake (in units of µg/day) from accessible surface sediment and crab tissue is calculated using the following equation:

$$uptake_i = \frac{Pb_i \times IR_i \times AF_i \times EF_i}{AT_i} \tag{2}$$

where:

i	=	Media: sed (sediment); fish (fish); crab (crab tissue)
Pb_i	=	Average media lead concentration (mg/kg)
IR_i	=	Media ingestion rate (g/day)
AF_i	=	Media Absorption fraction (dimensionless)
EF_i	=	Medium-specific Exposure frequency (days/year)
ATi	=	Media- specific Averaging time (days/year).

Once the adult PbB is determined, the geometric mean of the fetal blood lead concentration can be predicted thus:

$$PbB_{fetal} = PbB_{adult} \times R_{fetal/maternal} \tag{3}$$

where:

PbBfetal	=	Geometric mean of blood lead concentration among fetuses of adults (µg/dL)

2 https://www.epa.gov/superfund/lead-superfund-sites-frequent-questions-risk-assessors-adult-lead-methodology#ALM

Rfetal/maternal = Fetal/maternal blood lead ratio (dimensionless).

The 95th percentile of either the adult or fetal blood lead concentration can be calculated by simply multiplying the geometric mean by the geometric standard deviation of blood lead concentration:

$$PbB_{adult,0.95} = PbB_{adult} \times GSD^{1.645} \tag{4}$$

where:

PbBadult, 0.95 = 95th percentile of blood lead concentration among adults (µg/dL)

GSD = Geometric standard deviation of blood lead concentration (dimensionless).

E-4.1 Preliminary Remediation Goals

PRGs are calculated based on Equations 3 and 4 in USEPA (2003) using the following equation:

$$PRG_i = \frac{\left(\left[\frac{PbB_{fetal,0.95}}{R_{fetal/maternal} \times GSD^{1.645}}\right] - PbB_0\right) \times AT_i}{BKSF \times IR_i \times AF_i \times EF_i} \tag{5}$$

where:

i = Media: sed (sediment); fish (fish tissue); crab (crab tissue)

PRGi = Medium-specific Preliminary Remediation Goal (mg/kg)

PbBfetal,0.95 = 95th percentile blood lead concentration among fetuses of adults (µg/dL)

Rfetal/maternal = Fetal/maternal blood lead ratio (dimensionless)

GSD = Geometric standard deviation of blood lead concentration (dimensionless)

PbB0 = Baseline blood lead concentration (µg/dL)

ATi = Medium-specific Averaging time (days/year)

BKSF = Biokinetic slope factor [(µg/dL) per (µg/day)]

IRi = Media ingestion rate (g/day)

AFi = Media Absorption fraction (dimensionless)

EFi = Media- specific Exposure frequency (days/year).

E-4.2 Probability of Exceeding Target Fetal Blood Lead Level

The risk to the fetus can be estimated from the probability distribution of fetal PbB. In the ALM, the probability of exceeding the target blood lead level of concern (PbBt) is based on a lognormal probability model for PbBs in adult women, coupled with an estimated constant of proportionality between fetal and maternal blood lead levels (USEPA 2003). These relationships specify that the distribution of fetal PbB is lognormal (i.e., PbBfetal ~ Lognormal [GM, GSD]). Exceedance probabilities for the lognormal model can be determined after the GM of PbBfetal (from Equation 3), GSD, and exceedance criterion (PbBt) are converted to log scale, and a “standard normal deviate” or “z-value” is calculated as follows:

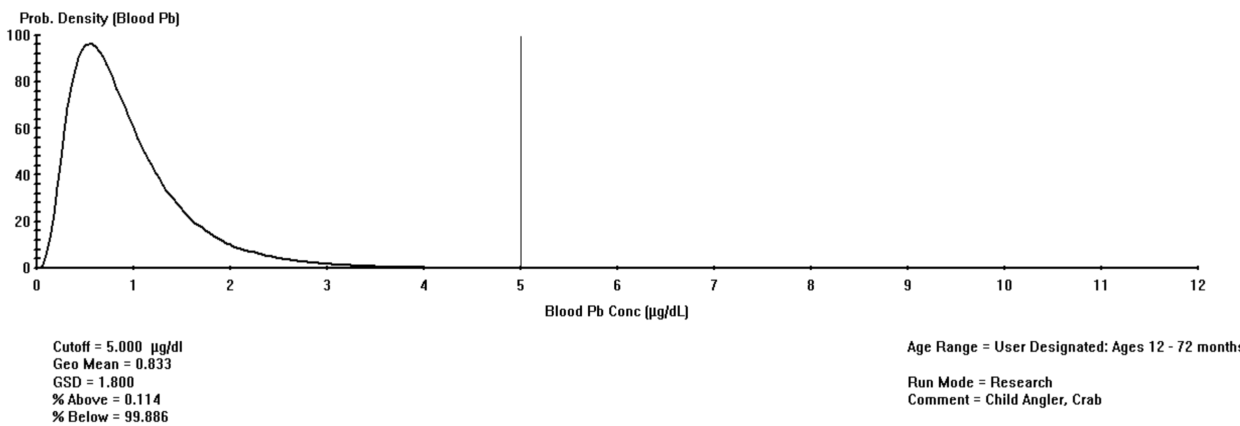
$$z = \frac{ln(PbB_t) - ln(GM)}{\ln(GSD)} \tag{6}$$

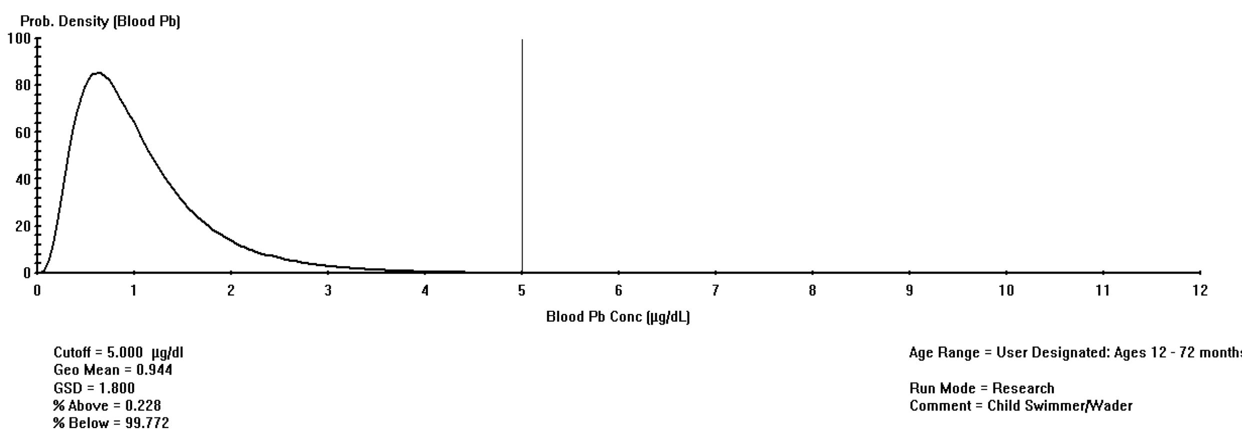
Using standard normal probability tables, the probability (p) of a lesser value than z can be identified. The probability that the PbBfetal exceeds PbBt is estimated as (1-p)×100 (USEPA, 2003). In this assessment, the PbBt was set to 5 µg/dL, which is the USEPA's target blood lead level used in the ALM spreadsheet (USEPA, 2017a) and subsequent ALM guidance (USEPA, 2017b), and consistent with the Centers for Disease Control (CDC) current reference value for lead (CDC, 2012). The current regulatory target is that no more than 5% of young children in a population have a blood-lead level exceeding 5 µg/dL (USEPA, 2017b).

E-5 Results

E-5.1 Children

The IEUBK model calculates a distribution of blood lead concentration in children. The results are presented in graphical format below, and the model output is provided in Attachment E-A. As can be seen in the figures below, <5% of child anglers/sportsmen, swimmers, and waders potentially exposed to lead under the conditions summarized above are predicted to have blood lead levels greater than 5 ug/dL (<1%). Therefore, under the conditions described above, no adverse health effects are expected for children potentially exposed to lead in accessible surface sediment or crab tissue at Newark Bay.





E-5.2 Adults

Based on the Bowers et al. (1994) model, the 95th percentile of predicted PbB levels in the fetus for all adolescent and adult receptors is below 5 µg/dL (0.46 to 3.44 µg/dL). In addition, <5% of fetuses potentially exposed to lead under the conditions summarized above are predicted to have blood lead levels greater than 5 ug/dL (0.009 to 1.1%). Finally, all media concentrations are below the calculated PRGs. The PbB and PRG calculations and assumptions for each receptor are provided in Table E¬3. Accordingly, under the conditions evaluated, no adverse health effects are expected for adults or adolescents, including their offspring, potentially exposed to lead in accessible surface sediment or crab tissue at Newark Bay.

E-6 Uncertainties

The IEUBK model is designed to simulate PbBs for children up to 84 months of age, which is different from the child receptor evaluated in the BHHRA (aged 1 to <7 years). Accordingly, the IEUBK evaluation was limited to 72 months, from the first birthday until the day before the seventh birthday. This difference is not expected to affect the conclusions of the evaluation.

As discussed above, in the main BHHRA report, child swimmers and waders under the RME scenario are assumed to be exposed to sediment 1 day per week for 3 months, or 13 days per year. However, the IEUBK model assumes exposure occurs for 365 days per year, and these assumptions cannot be changed in the model. Accordingly, an exposure frequency and averaging time of 365 days per year was used. The 365 days per year assumptions overstate the contribution of lead in sediment to child blood lead levels, and yield an even lower percentage of child swimmers and waders potentially exposed to lead who would be predicted to exhibit PbBs higher than 5 µg/dL than if the lower 13 days per year value was used.

Lead risk assessment methods are different from those used for other chemicals, because they use cumulative exposures to predict PbBs, rather than exposures to discreet sources. Accordingly, uncertainties are compounded by the many sources of exposure, in addition to uncertainties arising from the incidental ingestion of sediment and crab tissue.

Fetal risk estimates share common sources of uncertainties with the estimates for child risks, including the assumed crab lead concentrations and crab consumption rates. Uncertainties unique to the ALM include the assumed baseline blood lead level and geometric standard deviation parameters from the National Health and Nutrition Examination Survey (USEPA, 2017b). The results are based on the highest recommended values for the baseline blood lead levels and the geometric standard deviation. They are unlikely to underestimate risk. Blood lead levels for adolescents were evaluated using the ALM. This introduces some uncertainty to the evaluation; however, given the limitations of currently available modeling tools, USEPA states that it is reasonable to apply the ALM to adolescent receptors. To account for the potential that lead absorption is higher in adolescents than adults, the absorption fraction for lead in sediment was assumed to be 0.3 for adolescents, rather than the default of 0.12 for adults.

Potential exposure to lead in crab was evaluated based on the mean concentration of lead in hepatopancreas tissue (0.411 mg/kg) because this was the only tissue in which the maximum lead concentration exceeded the screening level. Had the assessment been done on the mean concentration in hepatopancreas and muscle combined (0.0553 mg/kg) or muscle only (0.0207 mg/kg), the estimated blood lead concentrations would have been even lower.

Finally, the mean concentration of lead in sediment of 205.7 mg/kg is approximately a factor of 10 lower than the maximum concentration of 2,190 mg/kg. Only one other value is over 1,000 mg/kg, and only 10 values are over 200 mg/kg. Accordingly, while it is possible that some individuals may be exposed to higher concentrations of lead in sediment on an intermittent basis, the difference is not expected to affect the conclusions of the evaluation.

E-7 References

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